October _/

PTO/SB/21 (08-03) Approved for use through 07/31/2006, OMB 6651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of Information unless it displays a valid OMB control number. Application Number 09/042,460 TRANSMITTAL Filing Date March 16, 1998 FORM First Named Inventor Gregg Morin, et al. Art Unit (to be used for all correspondence after initial filing) 1636 Examiner Name Sumesh Kaushal Attorney Docket Number 5 019/224P Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication Fee Transmittal Form Drawing(s) to Group Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to Group Petition Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a (in duplicate) After Final Proprietary Information Provisional Application Power of Attorney, Revocation Affidavits/declaration(s) Change of Correspondence Address Status Letter Other Endosure(s) (please Terminal Disclaimer Extension of Time Request Identify below): (in duplicate) Request for Refund Express Abandonment Request CD, Number of CD(s) Information Disclosure Statement Certified Copy of Priority Document(s) 1. Request for Examiner's Affidavit Pursuant to 37 CFR 1.104(d)(2) (4 pages) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm J. Michael Schiff, Registration No. 40,253 Individual name Signature Date 2023 CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being lacylimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. Typed or printed name Karen Makausky Date

This collection of information is required by 37 CFR 1.5. The Information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 223131450. ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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To:

Sumesh Kaushal, Ph.D.

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Number of pages including cover:

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Transmittal & Amendment for

USSN 09/042,460

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Makausky Name

Herlanz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of: Gregg Morin et al.

Serial No.: 09/042,460

Docket: 019/224p

Filing Date: March 16, 1998

For: MOUSE TELOMERASE

REVERSE TRANSCRIPTASE

Art Unit: 1636

Examiner: Sumesh Kaushal, Ph.D.

REQUEST FOR EXAMINER'S AFFIDAVIT PURSUANT TO 37 CFR § 1.104(d)(2)

Commissioner for Patents Alexandria VA 22313

Dear Sir:

Claims 20, 23, 26, and 31-34 of this application stand rejected under 35 USC § 112 ¶ 1 in the final Office Action dated August 26, 2003 (Paper No. 47). The rejection is apparently based on facts within the personal knowledge of the Examiner of this application, or his supervisors. Accordingly, applicant hereby submits a formal request for an Examiner's Affidavit, pursuant to 37 CFR § 1.104(d)(2) and MPEP § 2144.03.

PATENT 09/042,460 Docket 019/224

Reason for Requesting Affidavit

The Office Action dated August 26, 2003 indicates that the specification is enabling for isolated polynucleotide encoding a protein that has at least 90% sequence identity to SEQ. ID NO:2, but only providing the protein contains seven particular amino acid motifs.

Applicant has previously shown that functional variants of SEQ. ID NO:2 (in compliance with Example 14 of the USPTO training materials for the Written Description Guidelines) can be made without undue experimentation. The most recent Office Action rejects applicant's previous response, citing *In re Scarbrough*, 182 USPQ 1979 (CCPA) as standing for the proposition that applicant's argument alone cannot take the place of evidence lacking in the record.

This position overlooks the fact that accompanying applicant's previous response was an expert Declaration under 37 CFR § 1.132 by Dr. Gregg Morin. Under penalty of perjury, and with the understanding that willful false statements may jeopardize the validity of the application, Dr. Morin explained the following:

- A good deal of evidence obtained before and since the filing of this application indicates that variations of over 10% of the sequence should be well tolerated
- It is known that the motifs in telomerase and in other DNA polymerase enzymes can withstand mutation without losing function
- A large number of variants of the mouse TERT sequence could be made and screened for function in a straight-forward manner, using standard techniques, irrespective of the presence of the motifs.

In renewing his rejection of the claims under the enablement requirement, the Examiner reasserted the Office's position that all of the motifs are required in their entirety for activity to be present. However, the Office Action provides no publication or other evidence to support the contention that what Dr. Morin stated in his § 1.132 Declaration is wrong!

¹ MPEP § 2144.03 indicates that if the applicant traverses an assertion made in an Office Action, the examiner should cite a reference in support of his or her position.

PATENT 09/042,460 Docket 019/224

Remedy

In the absence of evidentiary support that contradicts Dr. Morin's Declaration, the reasoning behind rejection of the claims under the enablement requirement of § 112 ¶ 1 is apparently based on facts within the personal knowledge of the Examiner of this application, or his supervisors.

Accordingly, applicant requests an Affidavit to document these facts, for which we are entitled under 37 CFR § 1.104(d)(2)².

Applicant further petitions the Office to hold the requirement for responding to the most recent Office Action in abeyance until the Affidavit is provided, and reset the time for responding to run from the date of mailing of the Affidavit. A proper response can only be formulated once the facts contained in the Affidavit have been fully considered by the applicant and our experts².

In the alternative, applicant requests that the rejection of claims 20, 23, 26, and 31-34 of this application under 35 USC § 112 ¶ 1 be withdrawn, and a new Office Action or Notice of Allowability be issued, setting a new period to respond.

² 37 CFR § 1.104(d)(2) states: When the rejection of an application is based on facts within the personal knowledge of an employee of the office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons.

PATENT 09/042,460 Docket 019/224

No fee is believed payable with respect to this Request. Nevertheless, should the Patent Office determine that a fee is required for consideration of this paper, or that any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

J. Michael Schiff

Registration No. 40,253

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October 1, 2003

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